

### SECTION FOR THE PHYSICIAN

I am enrolled in the Prescribing Program for LOTRONEX, and I will continue to follow the requirements of the Program.

I, or a healthcare provider under a physician's direction, have given the patient named above:

- a copy of the Medication Guide for LOTRONEX, and instructed the patient to read it carefully before signing this Agreement, and to take it home.
- counseling about the benefits and risks of LOTRONEX.
- appropriate instructions for taking LOTRONEX.
- answers to all of the patient's questions about treatment with LOTRONEX.
- a prescription for LOTRONEX that has the program sticker affixed on it to alert pharmacists I am enrolled in the Prescribing Program for LOTRONEX.

*The patient signed the Patient-Physician Agreement in my presence after I counseled the patient, asked if the patient had any questions about treatment with LOTRONEX, and answered all questions to the best of my ability.*

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Name of Physician (print)

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Signature

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Date

*After the patient and the physician sign this Patient-Physician Agreement, give a copy to the patient and put the original signed form in the patient's medical record.*

### **PRESCRIBING PROGRAM FOR LOTRONEX™: PHYSICIAN ENROLLMENT FORM**

*The Prescribing Program for LOTRONEX was implemented to help reduce risks of serious gastrointestinal adverse events, some fatal, associated with this medicine. The program is intended to help physicians and their patients understand the benefits and risks of treatment with LOTRONEX in order to make fully informed decisions.*

I wish to participate in the Prescribing Program for LOTRONEX (PPL) and acknowledge that I have read the complete Prescribing Information for LOTRONEX and understand and will follow the requirements of the PPL described below.

- For safety reasons, LOTRONEX is approved only for women with severe, diarrhea-predominant irritable bowel syndrome (D-IBS) who have:
  - Chronic IBS symptoms (generally lasting for 6 months or longer),
  - had anatomic or biochemical abnormalities of the gastrointestinal tract excluded, and
  - not responded adequately to conventional therapy.

Diarrhea-predominant IBS is severe if it includes diarrhea and one or more of the following: